

**P A T E N T**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**


Applicant:	ALAN SHLUZAS et al.	Confirmation No.:	3377
Serial No.:	10/658,736	Examiner:	Nicholas W. Woodall
Filed:	SEPTEMBER 9, 2003	Group Art Unit:	3733
Docket No.:	1291.1138101	Customer No.:	28075
Title:	METHODS AND APPARATUSES FOR TREATING THE SPINE THROUGH AN ACCESS DEVICE		

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

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Kathleen L. Boekley

August 20, 2008  
Date

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

The rejection of claims 20-29 as being unpatentable over Mathews (US 6,033,406) in view of Luque (US 4,790,297) and Foley (US 5,792,044) and Davison (US 2001/0011170) is in error because the Examiner failed to provide the necessary reasoning to support the legal conclusion of obviousness. The Examiner acknowledges that Mathews fails to teach (1) performing a two level fixation procedure spanning two intervertebral spaces between three vertebrae, (2) advancing a decompression tool into the surgical site to perform a decompression procedure on the vertebrae, and (3) inserting an access device in a first configuration through an incision of the skin until a distal portion is located adjacent the spine and actuating the access device to a second configuration having an enlarged cross-sectional

area at the distal portion spanning at least a portion of the first, second, and third vertebrae, and performing the surgical procedures through the access device, as recited in the claims.

The Examiner relies on Luque for teaching a method of performing a two level fixation procedure and Davison for teaching a method involving inserting an access device, actuating the device to a configuration having an enlarged cross-sectional area at the distal portion spanning at least a portion of first, second, and third vertebrae, and performing various surgical procedures, such as decompression and fixation through the access device. The Examiner then asserts that it would have been obvious to one of ordinary skill in the art to perform the method of Mathews modified by Luque and Foley, through the access device of Davison in order to fix multiple joints of the spine, to reduce the pressure on the spinal cord, and to provide a larger working area while reducing the amount of trauma experienced by the patient. Applicants respectfully disagree. The Examiner appears to be relying on a number of references to teach various steps in the claimed method, but has not provided articulated reasoning with rational underpinning to support the conclusion of obviousness.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 decision. MPEP 2143.02 states that a reasonable expectation of success is required:

>A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1395 (2007); *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

Emphasis added. Applicants submit that the Examiner appears to have found individual pieces of the claim in the various references, but has not provided any reasoning to support an assertion that one skilled in the art could have combined Mathews, Luque, Foley, and Davison with no change in their respective function, and that such a combination would have yielded nothing more than predictable results. Applicants submit that one of ordinary skill in the art would have no reasonable expectation of success in attempting to perform the method steps of Luque through an access device of Davison. In particular, Luque teaches:

As a safety feature, a plurality of guide wires 17 are introduced through the cancellous bone. The guide wires 17 are expected to deflect if directed against the cortical bone. This perforation of the soft bone of the pedicle is always done under direct vision and introduced into the middle of the vertebral body.

...

A canulated screw tap 63 is then introduced over the guide wires 17 and through the pedicle to form a threaded aperture 64 in the vertebrae V as will now be apparent to those skilled in the art. ... If any guide wire 17 is bent or deformed, it must be removed and replaced with a straight guide wire 17 (passing the screw tap 63 or screw 15 over a bent guide wire 17 could cause the guide wire 17 to advance an undesirable distance).

...

With all the guide wires 17 aligned, the appropriate size plate 13 is then placed over the guide wires 17 so that all the guide wires 17 pass through the slot 23. ...Prior to seating the screws 15 into the plate 13, adjustments for lordosis, kyphosis compression or distraction are done with clamps or with a joy stick action with the driver 65 on the screws 15, individually and segmentally.

...

When adequate correction and alignment is obtained, the screws 15 are snugged down onto the corresponding concaved depressions 25 of the plate 13, each screw 17 fitting at the appropriate place and fixed firmly at the desired position. The guide wires 17 are then removed.

Emphasis added; see column 4, line 60 through column 5, line 42. Luque thus appear to teach their surgical procedure as involving the insertion of multiple guidewires, screws, and plates spanning multiple vertebrae. Luque appear to teach the simultaneous insertion of guidewires and screws into three or more vertebrae, and adjusting “for lordosis, kyphosis compression or distraction are done with clamps or with a joy stick action with the driver 65 on the screws 15”, as shown in FIG. 1.

In the Response to Arguments section on page 4 of the final Office Action, the Examiner states that Luque is not being used to teach performing a spinal fixation method

through an access device, but rather for teaching performing a known spinal method over multiple spinal joints to fix multiple joints of the spine together. However, claim 20 recites in part, “performing a two level fixation procedure spanning the first and second interbody spaces through the access device”. The Examiner has acknowledged that the primary reference, Mathews fails to teach such a step, and none of the other references are asserted as providing this teaching. Thus, if Luque is not being relied on for teaching or suggesting this method step, then none of the references teach the step and the rejection is in error for failing to teach or suggest all elements in the claim as required by MPEP 2143.03. Further, the Examiner contradicts this assertion in the arguments on page 5 by stating,

“the examiner believes that modifying the method of Mathews further performing a multilevel procedure in view of Luque in order to fix multiple spinal joints together...and further performing the know[n] spinal procedures through an access device actuated from a first configuration to a second configuration in view of Davison...is a proper combination that teaches all the limitations of the claims.”

The only rationale for making the asserted combination appears to be because one of ordinary skill could attempt the combination, which is not a proper basis for obviousness.

As shown in the above quotations from Luque, the reference appears to teach the simultaneous insertion of guidewires and screws into three or more vertebrae. Luque thus appears to teach away from performing such method steps through an access device such as that taught by Davison. Applicants submit that the Examiner has not provided any reasoning as to how or why one of ordinary skill in the art would attempt to perform such a method through an access device such as that taught by Davison. The Examiner asserts, on page 5 of the Final Office Action, “[t]he references do not explicitly teach that the procedures are not capable of being performed through an access device.” Applicants submit that this is not a proper basis for obviousness. As stated above with regard to the *KSR* decision, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Applicants submit that the mere fact that references do not explicitly teach that a specific modification cannot be done does not support a conclusion that it would have been obvious to make that modification. The rejection is thus in error.

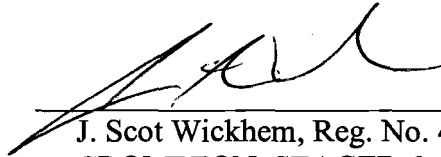
Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,

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By their attorney,

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